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Perchlorate Contamination of Drinking Water: Regulatory Issues and Legislative Actions

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Summary

Perchlorate is the explosive component of solid rocket fuel, fireworks, road flares, and other products. Used mainly by the Department of Defense (DoD) and related industries, perchlorate also occurs naturally and is present in organic nitrate fertilizer from Chile. This very soluble, persistent compound has been disposed of in the ground for decades and has been detected in sources of drinking water for more than 11 million people. It also has been found in milk, fruits, grains and vegetables. Thus, concern has increased about the potential health risks from perchlorate exposure. The Environmental Protection Agency's (EPA's) effort to make a determination whether to regulate perchlorate in drinking water has been slowed by uncertainties regarding the health effects of exposure at low levels and by the need for further research on occurrence and treatment technologies. Related issues include environmental cleanup and water treatment costs, which will be driven by federal and state standards. Because of scientific uncertainties and interagency disagreement regarding the risks of perchlorate exposure, several federal agencies asked the National Research Council (NRC) to assess perchlorate's health effects and the EPA's draft risk assessment. The NRC issued its report in January 2005, and the EPA has adopted the NRC's recommended reference dose (i.e., the expected safe dose) for perchlorate exposure. The reference dose provides a basis for developing a standard; however, the EPA has not decided to regulate perchlorate, and new studies raise more questions about what level of exposure might be safe. This report reviews perchlorate water contamination issues and related actions.

Background

Ammonium perchlorate is the key ingredient in solid fuel for rockets and missiles; other perchlorate salts are used to manufacture products such as fireworks, air bags, and road flares. Uncertainty about the health effects of perchlorate has slowed efforts to establish drinking water and environmental cleanup standards for it. However, because of perchlorate's persistence in water and ability to affect thyroid function, concern has escalated with the detection of perchlorate in water in at least 33 states. In the absence of a federal standard, states have begun to adopt their own measures. Massachusetts set a drinking water standard of 2 parts per billion (ppb, or micrograms per liter [μg/L]) in

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2006, and California has proposed a 6 ppb standard. Several states have issued health goals or advisory levels ranging from 1 ppb in Maryland (advisory level) and New Mexico (drinking water screening level) to 51 ppb in Texas (industrial cleanup level).

Occurrence. Perchlorate has been used heavily by the Department of Defense (DoD) and its contractors, and perchlorate contamination of water has been found most often near weapons and rocket fuel manufacturing facilities and disposal sites, research facilities, and military bases. Fireworks and other manufacturing facilities and construction sites also have been sources of contamination. Perchlorate also occurs naturally (in West Texas, for example) and is present in organic fertilizer imported from Chile.[1] In 1997, a new test method lowered the detection limit for perchlorate in drinking water from 400 parts per billion to 4 ppb, prompting several states to begin testing. Within two years, perchlorate was detected in drinking water sources for more than 11 million people in the Southwest and in surface and ground water in scattered locations across the country. Contamination has been found most often in ground water; however, it has been detected at low levels in the Colorado River, a major source of drinking water and irrigation water for Arizona, California, and Nevada.[2] Perchlorate also has been detected in dairy milk in various states, especially California and Texas.

In 1999, the EPA required public water systems to monitor for perchlorate under the Unregulated Contaminant Monitoring Rule to determine the frequency and levels at which it is present in public water supplies nationwide. The rule required monitoring by all water systems serving more than 10,000 persons and by a representative sample of smaller systems. Of some 3,700 water systems tested, perchlorate was detected in 153 systems in 26 states and 2 commonwealths.[3] Of those 153 systems, 14 had perchlorate levels above EPA's reference dose of 24.5 ppb.[4] The EPA also reported perchlorate contamination at 65 DoD facilities, 7 other federal facilities, and 37 private sites. In California, where most perchlorate releases have been identified, perchlorate has been detected at least twice in 276 sources of drinking water that supply 77 water systems.

Monitoring also has been undertaken to assess the presence of perchlorate in foods. In 2004, the Food and Drug Administration (FDA) tested 500 samples of foods, including vegetables, milk, and bottled water for perchlorate. Samples were taken in areas where

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[1] Purnendu K. Dasgupta, et al., "Perchlorate in the United States: Analysis of Relative Source Contributions to the Food Chain," *Environmental Science and Technology*, v. 40, n. 21, Nov. 21, 2006, p. 6608-6614. This study suggests that although Chilean fertilizer is a much smaller source of perchlorate than oxidizers, the fertilizer may have a proportionally greater impact as a source of perchlorate in the food chain because it is applied directly to crop land. This article reports that processing methods have reduced the perchlorate content of Chilean fertilizer in recent years.

[2] A key source of perchlorate in the Colorado River has been a facility in Nevada, where perchlorate production began in 1951. Since 1997, Nevada and the EPA have worked with Kerr McGee to control the source of releases. From January 2004 through June 2005, only three of the monthly samples had detectable levels of perchlorate. U.S. EPA, Region 9, *Perchlorate Monitoring Results: Henderson, Nevada to the Lower Colorado River*, June 2005.

[3] EPA, Federal Facilities Restoration and Reuse, *Known Perchlorate Releases in the U.S.*, Mar. 25, 2005, at [http://www.epa.gov/fedfac/documents/perchlorate_links.htm#occurrences].

[4] U.S. Government Accountability Office, *Perchlorate: A System to Track Sampling and Cleanup Results is Needed*, GAO-05-462, May 2005, p. 3.

water was thought to be contaminated. The FDA found perchlorate in roughly 90% of lettuce samples (average levels ranged from 11.9 ppb to 7.7 ppb for lettuces in four states), and in 101 of 104 bottled milk samples (with an average level of 5.7 ppb across 14 states). [5] This research is relevant to the EPA's standard-setting efforts, as EPA would take into account other exposures to perchlorate when setting a drinking water standard.

Health Effects. Perchlorate is known to disrupt the uptake of iodine in the thyroid, and health effects associated with perchlorate exposure are expected to parallel those caused by iodine deficiency. Iodine deficiency decreases the production of thyroid hormones, which help regulate the body's metabolism and growth. A key concern is that impairment of thyroid function in pregnant women can affect fetuses and infants and can result in delayed development and decreased learning capability. Several human studies have indicated that thyroid changes occur in humans at significantly higher concentrations of perchlorate than the amounts typically observed in water supplies.[6] However, a new study by the Centers for Disease Control and Prevention (CDC) of a representative sample of the U.S. population found that environmental exposures to perchlorate have an effect on thyroid hormone levels in women with iodine deficiency. No effect was found in men, but 36% of the women in this large study were found to be iodine deficient.[7] The median level of urinary perchlorate measured in 1,111 women in the study was 2.9 ppb.

EPA Regulation of Perchlorate

The EPA has taken steps toward establishing a standard for perchlorate in drinking water but has not made a determination to regulate it. Under the Safe Drinking Water Act (SDWA, §1412(b)), the EPA must establish a standard for a contaminant if the Administrator determines that the contaminant occurs at a frequency and level of public health concern and that its regulation presents a meaningful opportunity for reducing health risks. In 1997, when a better detection method became available for perchlorate and detections increased, scientific information was limited. In 1998, the EPA placed perchlorate on the list of contaminants that were candidates for regulation but concluded that information was insufficient to determine whether perchlorate should be regulated under the SDWA. The EPA listed perchlorate as a priority for further research on health effects and treatment technologies and as a priority for collecting occurrence data.

Perchlorate Risk Assessment. In 1992, and again in 1995, EPA issued draft reference doses (RfDs) for perchlorate exposure. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure that is not expected to cause any adverse, non-cancer health effects during a lifetime. In developing an RfD, the EPA incorporates factors to account for sensitive subpopulations, study duration, inter- and intraspecies variability, and data gaps. The draft RfDs range of 0.0001 to 0.0005

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[5] The FDA test results are available online at [http://www.cfsan.fda.gov/~dms/clo4data.html].

[6] Michael A. Kelsh et al., "Primary Congenital Hypothyroidism, Newborn Thyroid Function, and Environmental Perchlorate Exposure Among Residents of a Southern California Community," *Journal of Occupational Environmental Medicine*, 2003, p. 1117.

[7] Benjamin C. Blount, James L. Pirkle, et al., "Urinary Perchlorate and Thyroid Hormone Levels in Adolescent and Adult Men and Women Living in the United States," Centers for Disease Control and Prevention, in *Environmental Health Perspectives*, October 2006.

milligrams per kilogram (mg/kg) body weight per day translated to a drinking water equivalent level of 4 ppb-18 ppb. The EPA takes the RfD into account when setting a drinking water standard; it also considers costs, the capabilities of monitoring and treatment technologies, and other sources of perchlorate exposure, such as food.

The EPA continued to assess perchlorate risks, and its 1999 draft risk characterization resulted in a human risk benchmark of 0.0009 mg/kg per day (with a 100-fold uncertainty factor), which converted to a drinking water equivalent level of 32 ppb. However, the EPA determined that the available health effects and toxicity database was inadequate for risk assessment. In 1999, the EPA issued an *Interim Assessment Guidance for Perchlorate*, which recommended that EPA risk managers use the standing reference dose range and drinking water equivalent level (DWEL) of 4-18 ppb for perchlorate-related assessment activities at hazardous waste sites.

In 2002, the EPA completed a draft risk assessment that concluded that the potential human health risks of perchlorate exposures include effects on the developing nervous system and thyroid tumors, based on rat studies that observed benign tumors and adverse effects in fetal brain development. The document included a draft RfD of 0.00003 mg/kg per day, which translated to a drinking water equivalent level of 1 ppb. This document was controversial, both for its implications for cleanup costs and for science policy reasons. (For example, some peer reviewers expressed concern over the EPA's risk assessment methodology and reliance on rat studies.) The DoD, water suppliers, and other commentors expressed concern that the draft RfD could lead to unnecessarily stringent and costly cleanups of perchlorate releases at federal facilities and in water supplies. In 2002, a federal interagency perchlorate working group convened to discuss perchlorate risk assessment, research and regulatory issues, and related agency concerns. Working group members included the DoD, the EPA, the Department of Energy, the National Aeronautics and Space Administration, the Office of Science and Technology Policy, the Council on Environmental Quality, and the Office of Management and Budget.

NRC Perchlorate Study. To resolve some of the uncertainty and debate over perchlorate's health effects and the 2002 draft risk assessment, the interagency working group asked the National Research Council (NRC) to review the available science for perchlorate and EPA's draft assessment. The NRC was asked to comment and make recommendations. The NRC Committee to Assess the Health Implications of Perchlorate Ingestion issued its review in January 2005 and suggested several changes to EPA's draft risk assessment. The committee concluded that because of key differences between rats and humans, studies in rats are of limited use for quantitatively assessing human health risk associated with perchlorate exposure. Although the committee agreed that thyroid tumors found in a few rats were likely perchlorate treatment-related, it concluded that perchlorate exposure is unlikely to lead to thyroid tumors in humans. The committee noted that, unlike rats, humans have multiple mechanisms to compensate for iodide deficiency and thyroid disorders. Also, the NRC found flaws in the design and methods used in the rat studies. The committee concluded that the animal data selected by the EPA should not be used as the basis of the risk assessment.

The committee also reviewed the EPA's risk assessment model. It agreed that the EPA's model for perchlorate toxicity represented a possible early sequence of events after exposure, but it did not think that the model accurately represented possible outcomes after changes in thyroid hormone production. Further, the committee disagreed with the

EPA's definition of a change in thyroid hormone level as an adverse effect. Rather, the NRC defined transient changes in serum thyroid hormone as biochemical events that might precede adverse effects, and identified hypothyroidism as the first adverse effect.

Because of research gaps regarding perchlorate's potential effects following changes in thyroid hormone production, the committee made the unusual recommendation that EPA use a *nonadverse effect* (i.e., the inhibition of iodide uptake by the thyroid in humans) rather than an adverse effect as the basis for the risk assessment. The committee explained that "[i]nhibition of iodide uptake is a more reliable and valid measure, it has been unequivocally demonstrated in humans exposed to perchlorate, and it is the key event that precedes all thyroid-mediated effects of perchlorate exposure."[8] Based on the use of this point of departure, the reliance on human studies, and the use of an uncertainty factor of 10 (for intraspecies differences), the NRC's recommendations led to an RfD of 0.0007 mg/kg per day. The committee concluded that this RfD should protect the most sensitive population (i.e., the fetuses of pregnant women who might have hypothyroidism or iodide deficiency) and noted that the RfD was supported by clinical studies, occupational and environmental epidemiologic studies, and studies of long-term perchlorate administration to patients with hyperthyroidism.[9] In addition, the NRC identified data gaps and research needs. The committee has received some criticism for the extent to which it relied on a small, short-term human study, and debate over perchlorate's health risks continues.

EPA's Response. In 2005, the EPA adopted the NRC recommended reference dose of 0.0007 mg/kg per day, which translates to a drinking water equivalent level of 24.5 ppb. The DWEL is the concentration of a contaminant in water that is expected to have no adverse effects; it is intended to include a margin of safety to protect the fetuses of pregnant women who might have a preexisting thyroid condition or insufficient iodide intake. The DWEL is based on the assumption that all exposure would come from drinking water. If the EPA were to develop a drinking water standard for perchlorate, it would adjust the DWEL to account for other sources of exposure, such as food.

In January 2006, the EPA's Superfund office issued guidance adopting the NRC reference dose and the DWEL of 24.5 ppb as the recommended value to be considered as the preliminary remediation goal (PRG) to guide perchlorate assessment and cleanup at Superfund sites. In March, the EPA's Children's Health Protection Advisory Committee (CHPAC) wrote to the EPA Administrator that the PRG does not protect infants, who are highly susceptible to neurodevelopmental toxicity and may be more exposed to perchlorate than fetuses. The CHPAC noted that perchlorate is concentrated in breast milk and that nursing infants could receive daily doses greater than the RfD if the mother is exposed to 24.5 ppb perchlorate in tap water. The committee recommended that the Superfund office lower the PRG and that the Office of Water develop a drinking water standard for perchlorate and, in the interim, issue a drinking water health advisory that takes into account early life exposures. CHPAC's assessment, combined with the new CDC study and ongoing data gaps, could further complicate EPA regulatory efforts.

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[8] National Research Council, *Health Implications of Perchlorate Ingestion*, Committee to Assess the Health Implications of Perchlorate Ingestion, National Academy of Sciences, 2005, p. 9.

[9] Ibid., p. 10.

Department of Defense

Having the largest number of identified sites with perchlorate contamination, the DoD has been under state and congressional pressure to address perchlorate releases. Cleanup has proceeded at some sites; however, cleanups typically are driven by drinking water standards or other established cleanup standards. With no federal standard and just one promulgated state standard, cleanup goals and responsibilities have been ambiguous. In January 2006, following EPA's establishment of a reference dose and DWEL for perchlorate, the DoD adopted a policy that establishes 24 ppb as the level of concern to be used in managing perchlorate releases, unless a more stringent federal or state standard has been promulgated. (In Massachusetts, for example, the drinking water standard of 2 ppb would apply). The new policy applies broadly to DoD installations and former military lands, and under it, the services are directed to test for perchlorate when it is reasonably expected that a release has occurred. If perchlorate levels exceed 24 ppb, a site-specific risk assessment must be conducted, and if the assessment indicates that the perchlorate could result in adverse health effects, then the site must be prioritized for risk management.[10] The DoD uses a relative risk site evaluation framework across DoD to evaluate the risks posed by one site relative to other sites. The DoD uses this framework to help prioritize environmental restoration work and to allocate resources accordingly.

The DoD has tested at least 800 sites at 101 facilities. Through FY2006, the DoD had spent roughly $88 million on perchlorate-related research activities, including $64 million on treatment technologies, $9.5 million on health and toxicity studies, and $11.6 million on pollution prevention. Additional funds have been spent on testing and cleanup.

Congressional Actions

The 109th Congress has targeted some funding for perchlorate cleanup in conference reports for various appropriations acts, including DoD and EPA appropriations acts for FY2006 (P.L. 109-148 and P.L. 109-54, respectively). In the conference report for the Department of Health and Human Services FY2006 appropriations act (P.L. 109-149), conferees encouraged the National Institute for Environmental Health Sciences to support studies on the long-term health effects of perchlorate. The conference report for the FDA's FY2006 funding act (P.L. 109-97) directs the FDA to continue conducting perchlorate surveys of food and bottled water and to report back to Congress. An array of bills focus on California, where most contamination has been found. The House has passed two bills to address perchlorate contaminated groundwater in California: H.R. 186 would authorize the Secretary of the Interior to make grants to the Santa Clara Valley Water District for groundwater remediation projects, and H.R. 18 would authorize such grants for water authorities within the Santa Anna River watershed. H.R. 3053 also would authorize funding for perchlorate remediation in Santa Clarita. H.R. 4798 and S. 2298 would authorize appropriations for a California Perchlorate Cleanup Fund to provide grants for remediating perchlorate contaminated drinking water sources and supplies; these bills also express the sense of Congress that the EPA should establish a drinking water standard for perchlorate. H.R. 213 would require the EPA to issue a perchlorate drinking water standard in 2007.

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[10] For more information, see the DoD perchlorate website regarding policy and guidance, [http://www.denix.osd.mil/denix/Public/Library/MERIT/Perchlorate/efforts/policy/index.html].